

EXHIBIT H



Clinical study

A prospective randomised study comparing the jubilee dressing method to a standard adhesive dressing for total hip and knee replacements

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KEYWORDS

Wound complication;
Wound dressing;
Jubilee method

Abstract *Aim of the study:* It is important to reduce potential wound complications in total hip and total knee arthroplasty procedures. The purpose of this study was to compare the jubilee dressing method to a standard adhesive dressing.

Method: 124 patients (62 total hip replacements and 62 total knee replacements) were randomly selected to have either a standard adhesive dressing or jubilee method dressing. The number of dressing changes, incidence of blistering, leakage, appearance of inflammation, infection rate and the average stay in hospital was recorded for each patient.

Results: The jubilee dressing significantly reduced the rate of blistering, leakage and number of dressing changes when compared to a traditional adhesive dressing ($p < 0.05$). The rate of inflammation and average length of stay in hospital was not significantly different between the two groups.

Conclusion: The authors recommend the use of this dressing for total hip and total knee arthroplasty procedures due to the associated lower complication rate.

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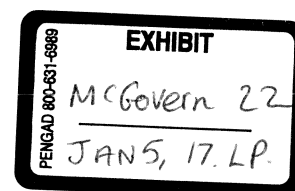
Background

Primary total hip arthroplasty (THA) and total knee arthroplasty (TKA) are commonly performed

orthopaedic procedures [1]. The incidence of infection for THA and TKA is between 0.39% and 1.26% [2–5]. Wound complications such as persistent leakage and blistering are also frequently reported [6–9]. These complications can lead to a longer hospital stay, extensive periods on intravenous antibiotics and the need for revision surgery. This increases the economic burden on

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the health service, and also causes significant psychological stress and anxiety to the patient.

Surgeons should be careful as regards to their choice of wound dressing. The use of traditional adhesive wound dressings are been associated with a blistering, with rates as high as 19.5% [10]. The jubilee method of wound dressing involves a hydrofiber inner layer which is highly absorbent, and a hydrocolloid viscoelastic outer layer (Fig. 1). In a previous study this method has been shown be beneficial with a significant reduction in the blister rate to 3.5% [10].

This aim of this prospective study was to evaluate the clinical benefits and cost effectiveness of the jubilee method compared to the standard traditional adhesive dressing.

Methods

Institution review board approval was granted for this study. Patients undergoing elective total hip replacement and total knee replacement in Cappagh



Figure 1 Post-operative jubilee dressing following a total knee replacement.

National Orthopaedic Hospital, Dublin were selected for participation over a nine month period in 2009. Informed consent by all the patients was obtained.

Patients undergoing revision surgery were excluded from this study. Also excluded were patients on immune-suppressants (e.g. methotrexate), with chronic skin conditions, (e.g. eczema, psoriasis), or those with trophic skin changes (e.g. diabetes, peripheral vascular disease).

Patients were selected using the block randomisation method to have either the jubilee dressing or a traditional adhesive dressing applied to their surgical wound. Each dressing was applied using aseptic technique at the end of surgery by the surgeon and then if required on the ward by a nurse trained in the application of these dressings.

The jubilee dressing consisted of a hydrofiber inner layer derived from 100% sodium carboxymethyl cellulose (Aquacel, ConvaTec) with a viscoelastic hydrocolloid outer layer which is vapour permeable (DuoDerm, ConvaTec). This outer dressing was applied with no tension by laying the dressing over the wound without stretching it. The comparison group had a simple dressing applied which had a self-adhesive outer aspect with a centrally located absorbent wound pad (Mepore, Molnlycke Health Care). The TKA patients in both groups also had a layer of wool and crep from the suprapatellar region of the knee to below the tibial tuberosity applied. This was removed on day 1 post-op. Dressing were changed only when there was a more than a 50% strikethrough of the inner layer visible. The number of dressing changes, incidence of blistering, leakage, appearance of inflammation and the average stay in hospital was recorded for each patient. The infection rate was also recorded. An erythematous, indurated wound with persistent copious discharge was suggestive of a deep surgical site infection.

The Mann–Whitney *U* test was used to statistically compare the number of dressing changes and the Two-Tailed test was used to compare the rate of blistering, infection, inflammation and leakage. A 5% statistical significance level was prescribed ($p < 0.05$).

Results

Over the nine month period 124 patients underwent total hip or total knee arthroplasty by two consultants. A midline incision was used for all total knee replacements and a posterior approach for all total hip replacements. Post-operatively 62 patients had the jubilee dressing applied (35 THA, 27 TKA), and 62 patients received the standard adhesive dressing (35 THA, 27 TKA). There were 77

Table 1 Wound complications and number of dressing changes for the two different types of dressing.

| | Jubilee dressing (n = 62) | Standard adhesive dressing (n = 62) |
|------------------------------|---|---|
| Blistering | 3 (4.8%) | 11 (17.7%)* |
| Leakage | 4 (6.4%) | 13 (20.9%)* |
| Inflammation | 3 (4.8%) | 3 (4.8%) |
| Infection | 0 (0%) | 0 (0%) |
| Mean no. of dressing changes | 1 = 38 (62%) 2 = 19 (29%) 3+ = 5 (8%) | 1 = 8 (13%)* 2 = 35 (56%)* 3+ = 19 (31%)* |

(* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$).

male and 47 female patients, with a mean age at the time of surgery of 67 years. The average patient stay was 9 days inclusive following surgery.

Table 1 shows the results for the number of wound blisters, number of dressing changes, leakage, inflammation and the infection rate for the two types of post-operative dressing. Wound blistering was reduced using the jubilee method (4.8%) compared to the standard adhesive dressing (17.7%; $p < 0.04$). Leakage was also significantly decreased using the jubilee dressing (6.4 vs 20.9%; $p < 0.034$). The number of dressing changes prior to discharge was significantly less, with 62% of patients using the jubilee method requiring only one dressing change, compared to 13% ($p < 0.03$). No patients developed a deep infection. Subjective assessment of wound inflammation between the two groups showed no significant difference and the average in-patient stay was the same for both groups (9 days; range 4–16). No outcome differences were noted between those patients that underwent total hip replacement and the total knee replacement ($p > 0.05$). The average total cost of the jubilee dressing used during their hospital stay for was 26.48 euro, while the standard adhesive dressing was 12.97 euro.

Discussion

Surgical technique with careful tissue handling is important in wound healing, as well as the type of dressing that is applied post-operatively [6,11]. The hydrofiber/hydrocolloid dressing combination showed significant clinical improvement compared to the adhesive dressing. The authors advocate this post-operative dressing for primary hip and knee arthroplasty procedures.

The rates of blistering using the jubilee method in this study were slightly higher in comparison with another similar study [10]. However, both studies showed significantly reduced blistering compared to using the traditional adhesive dressing. It has been suggested that the blister

rate is less due to the ability of the hydrocolloid layer to stretch [12,13]. During hip or knee motion, the skin expands and contracts and the jubilee dressing is able to accommodate this movement more easily and so the reduce the frictional forces between the skin and dressing may be less.

The significant reduction in the leakage or exudate from the wound by the jubilee dressing is due to the absorbent hydrofiber inner layer. This would also lead to a decrease in the number of dressing changes required which was demonstrated in this study. The cost of the jubilee dressing may be more than the traditional adhesive dressing, but the wound complication rate is significantly less with regards to blistering and leakage. This may prevent potential skin breakdown and the creation of an entry point for infection, but to date no study has shown this.

One limitation of this study was that it only followed-up patients during their stay in hospital. Another was that the dressing after the patient's hospital stay may have been changed by the district nurse to a different type. The presence of surgical wound inflammation may have been subjective, but was recorded for each case by the same tissue viability nurse to ensure consistency.

Conclusion

This prospective randomised study showed the jubilee dressing method had a lower complication rate when compared to a simple adhesive dressing. We recommend the use of this dressing for total hip and knee replacements during the hospital stay of the patient but also for use by the community nurse upon discharge, but further longer term follow-up is needed.

Conflicts of interest

The authors declare they have no competing interests study.

Acknowledgements

None.

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